

### **REMARKS**

The Official Action dated January 26, 2007 has been carefully considered. Accordingly, the amendments presented herewith, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

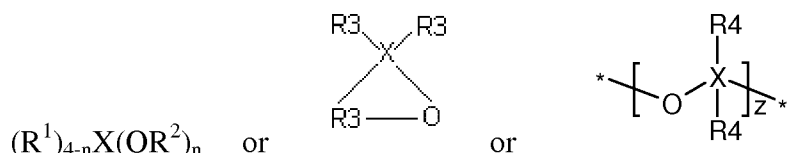
By the present Amendment, claims 2-3 and 17-18 have been cancelled. Independent claims 1, 16, 31 and 32 have been amended to correct a typographical error and to further define the features thereof. Claims 3 and 18 have been amended to change their dependency from cancelled claims 4 and 19 to claims 1 and 16, respectively. Finally, claims 12 and 27 have been amended to delete the term "solventless." These changes do not involve introduction of new matter. Therefore, entry is believed to be in order, and is respectfully requested.

Claims 1, 3-16, and 18-32 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner asserted that the claims are indefinite in that the definition of  $R^4$  includes in its definition compounds having the formula -  $(OSiR^4_2)_y-OSiR^4_3$  and thus defines the group itself. In addition, the Examiner asserted that claims 12 and 27 recite "wherein the reaction is conducted in ...a solventless condition" and it is unclear how an enzymatic reaction can be conducted without a solvent. Applicants traverse the rejection of the Examiner; however, to expedite prosecution of the application, claims 1, 16, 31, and 32 have been amended to clarify the definition of  $R^4$  and claims 12 and 27 have been amended to delete the term "solventless." Accordingly, it is submitted that the rejection of claims 1, 3-16, and 18-32 under 35 U.S.C. §112, second paragraph, has been overcome. Reconsideration is respectfully requested.

Claims 1, 3-16, and 18-32 were rejected under 35 U.S.C. §112, first paragraph, because the Examiner asserted that the specification does not reasonably provide enablement for forming any organic compound by reacting any organic reactant or organic intermediate as defined in

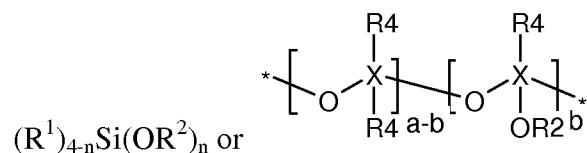
original claims 1, 16, 31 and 32 with any hydrolase enzyme. However, as set forth in detail below, Applicants submit that the methods defined by claims 1, 3-16, and 18-32 are fully enabled to one of ordinary skill in the art in accordance with the requirements of 35 U.S.C. §112, first paragraph. Accordingly, this rejection is traversed, and reconsideration is respectfully requested.

More particularly, claim 1 is directed to a method of forming an organic molecule, comprising contacting a hydrolase enzyme with an organic reactant, wherein: the organic reactant comprises the formula:



wherein: X is selected from the group consisting of silicon and germanium;  $R^1$  is selected from the group consisting of alkyl, haloalkyl, unsaturated alkyl, aryl, alcohol, epoxy, ether, amine,  $-(OXR^4)_y-OXR^4_3$ , and a combination thereof;  $R^2$  is selected from the group consisting of alkyl, hydrogen, ether and a combination thereof;  $R^3$  is selected from the group consisting of alkyl, unsaturated alkyl, aryl, hydrogen and a combination thereof;  $R^4$  is selected from the group consisting of alkyl, haloalkyl, unsaturated alkyl, aryl, hydrogen, hydroxy, alkoxy, alcohol, epoxy, ether, amine,  $-(OSiR^5)_y-OSiR^5_3$  and a combination thereof;  $R^5$  is selected from the group consisting of alkyl, haloalkyl, unsaturated alkyl, aryl, hydrogen, hydroxy, alkoxy, alcohol, epoxy, ether, amine, and a combination thereof; n is an integer from 0 to 4; y is 0 or is an integer greater than 0; and z is 3 or is an integer greater than 3; the hydrolase enzyme comprises lipase, protease, cutinase or a combination thereof; the lipase enzyme is selected from the group consisting of *Candida antarctica* lipase, *Candida antarctica* lipase B, *Rhizomucor miehei* lipase, wheat germ lipase or a combination thereof, the protease enzyme and is selected from the group consisting of trypsin, papain, pepsin or a combination thereof; and the hydrolase enzyme catalyzes the hydrolysis and condensation of the organic reactant to form the organic molecule. Independent claim 16 is directed to a method of forming organosilicon molecules and independent claim 31 is directed to a method of forming an organosilicon intermediate molecule.

Independent claim 32 is directed to a method of forming an organosilicon molecule, comprising contacting a hydrolase enzyme with an organosilicon intermediate reactant, wherein: the organosilicon intermediate reactant comprises the formula:



wherein:  $R^1$  is selected from the group consisting of alkyl, haloalkyl, unsaturated alkyl, aryl, alcohol, epoxy, ether, amine,  $-(OSiR^4)_y-OSiR^4_3$ , and a combination thereof;  $R^2$  is a hydrogen;  $R^3$  is selected from the group consisting of alkyl, unsaturated alkyl, aryl, hydrogen and a combination thereof;  $R^4$  is selected from the group consisting of alkyl, haloalkyl, unsaturated alkyl, aryl, hydrogen, hydroxy, alkoxy, alcohol, epoxy, ether, amine,  $-(OSiR^5)_y-OSiR^5_3$  and a combination thereof;  $R^5$  is selected from the group consisting of alkyl, haloalkyl, unsaturated alkyl, aryl, hydrogen, hydroxy, alkoxy, alcohol, epoxy, ether, amine, and a combination thereof;  $n$  is an integer from 0 to 4; and  $y$  is 0 or is an integer greater than 0;  $a + b$  equals  $z$ ;  $z$  is 3 or is an integer greater than 3; the hydrolase enzyme comprises lipase, protease, cutinase or a combination thereof; the lipase enzyme is selected from the group consisting of *Candida antarctica* lipase, *Candida antarctica* lipase B, *Rhizomucor miehei* lipase, wheat germ lipase or a combination thereof; the protease enzyme and is selected from the group consisting of trypsin, papain, pepsin or a combination thereof; and the hydrolase enzyme catalyzes the condensation of the organosilicon intermediate reactant to form the organosilicon molecule.

The specification provides various examples of monofunctional and polyfunctional organic reactants (see paragraph 0038) that may be contacted with hydrolase enzymes (see paragraph 0039) to catalyze the formation of an organic molecule. Accordingly, the claims are commensurate in scope with the enablement provided by the specification. As a matter of Patent Office practice, a specification which contains a teaching of a manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of section 12 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on enabling support, *In re Marzocchi*, 169 U.S.P.Q. 367, 369 (CCPA 1971) (emphasis by court).

The Examiner asserted that the specification provides evidence that most hydrolase enzymes did not catalyze the hydrolysis or condensation of any organic silane. In addition, the Examiner asserted that the specification shows that the vast majority of combinations of enzymes and organic reactants are unsuccessful. However, there is no disclosure in any of the examples for which a hydrolase enzyme, as defined by the claims, was not able to catalyze the hydrolysis or condensation of an organic reactant. The claims recite that the hydrolase enzyme comprises lipase, protease, cutinase or a combination thereof; wherein the lipase enzyme is selected from the group consisting of *Candida antarctica* lipase, *Candida antarctica* lipase B, *Rhizomucor miehei* lipase, wheat germ lipase or a combination thereof, and wherein the protease enzyme and is selected from the group consisting of trypsin, papain, pepsin or a combination thereof. These hydrolase enzymes are shown in Table 2 of the specification to catalyze the hydrolysis or condensation of an organic reactant. Therefore, the Examiner has not provided any objective evidence of record that the present claims are not enabled by the specification.

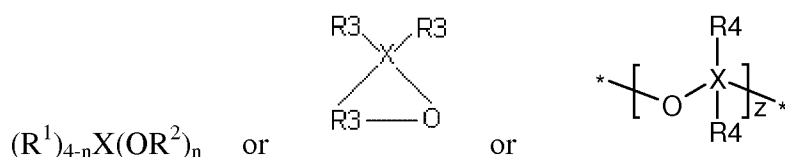
A disclosure is enabling if, from the information set forth in the specification, coupled with information known in the art, one of ordinary skill in the art could make and use the invention without undue experimentation, *United States v. Teletronics, Inc.*, 8 U.S.P.Q.2d 1217, 1224 (Fed. Cir. 1988). Moreover, every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification; rather, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention, *Genetech v. Novo Nordisk, A/S*, 42 U.S.P.Q.2d 1001, 1005 (Fed. Cir. 1997). Furthermore, Applicants are not required to disclose every embodiment encompassed by their claims, even in an unpredictable art. *In re Angstadt*, 190 U.S.P.Q. 214 (CCPA 1976). As the specification clearly defines the organic reactants, the hydrolase enzymes, and the Examiner has not provided any objective evidence of record that the present claims are not enabled, the present specification must be taken as in compliance with 35 U.S.C. §112, first paragraph, *In re Marzocchi*, 169 U.S.P.Q. 367 (CCPA 1971).

It is therefore submitted that claims 1, 3-16, and 18-32 are fully enabled by the specification, whereby the rejection under 35 U.S.C. §112, first paragraph, has been overcome. Reconsideration is respectfully requested.

Claims 1, 3-16 and 18-32 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner asserted that the claims are directed to methods of using a genus of organic reactants and a genus of hydrolases to produce a genus of organic compounds; however, the specification fails to describe representative species encompassed by the genus of the claim.

However, as will be set forth in detail below, Applicants submit that the methods defined by claims 1, 3-16, and 18-32 are fully defined by the specification in accordance with the requirements of 35 U.S.C. §112, first paragraph. Accordingly, this rejection is traversed, and reconsideration is respectfully requested

The organic reactants and hydrolase enzymes employed in the methods of the present invention are clearly defined by the specification. As set forth in the claims, the organic reactants comprise the formula:



wherein: X is selected from the group consisting of silicon and germanium;  $R^1$  is selected from the group consisting of alkyl, haloalkyl, unsaturated alkyl, aryl, alcohol, epoxy, ether, amine,  $-(OXR^4)_y-OXR^4$ , and a combination thereof;  $R^2$  is selected from the group consisting of alkyl, hydrogen, ether and a combination thereof;  $R^3$  is selected from the group consisting of alkyl, unsaturated alkyl, aryl, hydrogen and a combination thereof;  $R^4$  is selected from the group consisting of alkyl, haloalkyl, unsaturated alkyl, aryl, hydrogen, hydroxy, alkoxy, alcohol, epoxy, ether, amine,  $-(OSiR^5)_y-OSiR^5$  and a combination thereof;  $R^5$  is selected from the group consisting of alkyl, haloalkyl, unsaturated alkyl, aryl, hydrogen, hydroxy, alkoxy, alcohol, epoxy, ether, amine, and a combination thereof; n is an integer from 0 to 4; y is 0 or is an integer greater than 0; and z is 3 or is an integer greater than 3.

The claims also recite that the hydrolase enzyme comprises lipase, protease, cutinase or a combination thereof; wherein the lipase enzyme is selected from the group consisting of *Candida antarctica* lipase, *Candida antarctica* lipase B, *Rhizomucor miehei* lipase, wheat germ lipase or a combination thereof, and wherein the protease enzyme and is selected from the group consisting of trypsin, papain, pepsin or a combination thereof. By using the hydrolase enzymes defined in the claims, the hydrolase enzyme catalyzes the hydrolysis and condensation of the organic reactant to form the organic molecule.

Not only are the organic reactants and hydrolase enzymes clearly defined in the claims and the specification, the reaction sequences are also clearly defined. Specifically, at paragraphs 0034-0035 of the specification, the reaction sequences for each organic reactant formula recited in the claims are illustrated. As the specification clearly defines the organic reactants, the hydrolase enzymes, the present specification must be taken as in compliance with 35 U.S.C. §112, first paragraph.

As the specification clearly defines the organic reactants, the hydrolase enzyme, the present specification must be taken as in compliance with 35 U.S.C. §112, first paragraph.

It is therefore submitted that claims 1, 3-16, and 18-32 are fully defined by the specification, whereby the rejection under 35 U.S.C. §112, first paragraph, has been overcome. Reconsideration is respectfully requested.

Claims 1, 5, 9-16, 20 and 24-32 were rejected under 35 U.S.C. §102(b) as being anticipated by Friedrich, WO 02/22842. The Examiner asserted that Friedrich teaches the formation of organic siloxanes from a variety of organic silanes using an enzymatic hydrolysis and condensation with a lipase in aqueous or organic solvents at neutral pHs and temperatures of about 25 °C. The organic silanes used included phenyltriethoxysilane and tetrabutoxysilane.

However, as set forth in detail below, Applicants submit that the methods recited in claims 1, 5, 9-16, 20 and 24-32 are not anticipated by Friedrich. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

More particularly, independent claims 1, 16 and 31-32 are respectively directed to methods of forming an organic molecule, methods of forming organosilicon molecules, a method of forming an organosilicon intermediate molecule, and a method of forming an organosilicon molecule.

Friedrich discloses the polycondensation of organic silicon compounds in the presence of a lipase enzyme. Friedrich discloses that all lipases are suitable for the process of his present invention and preferred lipases are from the *Pseudomonas* species (see page 2, lines 10-11 of CA 2,422,600 English translation of WO 02/22842). In contrast, Applicants' claims recite that the lipase enzymes are selected from the group consisting of *Candida antarctica* lipase, *Candida antarctica* lipase B, *Rhizomucor miehei* lipase, wheat germ lipase or a combination thereof. The claims specifically recite these lipase enzymes, as other lipase enzymes are not able to catalyze the hydrolysis and condensation of organic reactants pursuant to the methods recited in the claims. In fact, Table 2 of the present application sets forth a variety lipase enzymes that are not able to catalyze the hydrolysis and condensation of an organic reactant. Included within this Table are *Pseudomonas cepacia* lipase and *Pseudomonas fluorescens* lipase, which are preferred lipase enzymes of Friedrich. Accordingly, as Friedrich teaches the use of enzymes that are not suitable for the methods of the present invention, Applicants submit that there is no teaching in Friedrich of the methods as defined by the claims.

"To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter, *PPG Industries Inc. v. Guardian Industries Corp.*, 37 U.S.P.Q. 2d 1618 (Fed. Cir. 1996). The disclosure must be enabling to have placed it in the possession of a person of ordinary skill in the field of the invention, *In re Paulsen*, 31 U.S.P.Q. 2d 1671 (Fed. Cir. 1994). Furthermore, a generic disclosure does not by itself describe Applicants' claimed invention within the meaning of 35 U.S.C. §102. Rather, such a prior art reference must further provide a more specific, limited teaching in order to anticipate, *In re Petering*, 133 U.S.P.Q. 275 (CCPH 1962); *In re Ruschig*, 145 USPQ 274 (CCPA 1965); and *In re Arkley*, 172 U.S.P.Q. 524 (CCPA 1972). In view of the

failure of Friedrich to teach or recognize the methods as defined by claims 1, 5, 9-16, 20 and 24-32, the reference does not enable one skilled in the art to practice the specific methods as recited in the claims. It is therefore submitted that Friedrich does not anticipate claims 1, 5, 9-16, 20 and 24-32 under 35 USC §102.

Applicants submit that the rejection under 35 USC §102 has been overcome. Reconsideration is respectfully requested.

Claims 1, 5, 9-16, 20 and 24-32 were rejected under 35 U.S.C. §102(b) as being anticipated by Cha et al (*Silicatein filaments and subunits from a marine sponge direct the polymerization of silica and silicones in vitro*). The Examiner asserted that Cha et al teach the formation of phenylsilsesquioxane from tetraethoxysilane using an enzymatic hydrolysis and condensation with the proteases trypsin, papain or silacatein in aqueous buffer at neutral pHs and temperatures of 20°C.

However, as will be set forth in detail below, Applicants submit that the methods defined by claims 1, 5, 9-16, 20 and 24-32 are not anticipated by Cha et al. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

More particularly, independent claims 1, 16 and 31-32 are respectively directed to methods of forming an organic molecule, methods of forming organosilicon molecules, a method of forming an organosilicon intermediate molecule and a method of forming an organosilicon molecule.

The Cha et al reference discloses that silicatein catalyzes the polymerization of silica. In contrast, the present claims are directed to methods of forming organic molecules by contacting a hydrolase enzyme with an organic reactant to catalyze the hydrolysis and/or condensation of the organic reactant to form the organic molecule. The hydrolase enzymes employed comprise lipase, protease, cutinase or a combination thereof; wherein the lipase enzyme is selected from the group consisting of *Candida antarctica* lipase, *Candida antarctica* lipase B, *Rhizomucor miehei* lipase, wheat germ lipase or a combination thereof; and wherein the protease enzyme and



is selected from the group consisting of trypsin, papain, pepsin or a combination thereof. The claimed methods do not employ silicatein as described by Cha et al.

The Examiner asserted that Cha et al teach the formation of organic molecules using protease enzymes including trypsin, papain or silacatein. However, Cha et al disclose that trypsin and papain do not catalyze the polymerization of silica. Specifically, as set forth in Table 1 of Cha et al, papain and trypsin report less reactivity with silica than the non-specific protein BSA control. In addition, as disclosed in Table 2 of the present application, the BSA control is also shown as not being able to catalyze the reaction as compared with the protease enzymes. Accordingly, Applicants find no teaching or reference in Cha et al of the methods of forming organic reactants, specifically, wherein the protease enzymes are selected from the group consisting of trypsin, papain, pepsin or a combination.

"To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter, *PPG Industries Inc. v. Guardian Industries Corp.*, supra. The disclosure must be enabling to have placed it in the possession of a person of ordinary skill in the field of the invention, *In re Paulsen*, supra. Furthermore, a generic disclosure does not by itself describe Applicants' claimed invention within the meaning of 35 U.S.C. §102. Rather, such a prior art reference must further provide a more specific, limited teaching in order to anticipate, *In re Petering*, supra; *In re Ruschig*, supra; and *In re Arkley*, supra. In view of the failure of Cha et al to teach or recognize the methods as defined by claims 1, 5, 9-16, 20 and 24-32, the reference does not enable one skilled in the art to produce the methods as recited by the claims. It is therefore submitted that Cha et al do not anticipate claims 1, 5, 9-16, 20 and 24-32 under 35 USC §102.

Applicants submit that the rejection under 35 USC §102 has been overcome. Reconsideration is respectfully requested.

Claims 1, 5, 9-16, 20 and 24-32 were rejected under 35 U.S.C. §102(a) or (e) as being anticipated by Sakkab, U.S. Published Patent Application No. 2003/0119156 A1. The Examiner asserted that Sakkab teaches the formation of organic siloxanes from a variety of organic silanes

using an enzymatic hydrolysis and condensation with a modified subtilisin in aqueous or organic solvents at neutral pHs and temperatures of about 25°C.

However, as set forth in detail below, Applicants submit that the methods defined by claims 1, 5, 9-16, 20 and 24-32 are not anticipated by Sakkab. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

More particularly, independent claims 1, 16 and 31-32 are respectively directed to methods of forming an organic molecule, methods of forming organosilicon molecules, a method of forming an organosilicon intermediate molecule and a method of forming an organosilicon molecule.

Sakkab disclose the biosynthesis of cyclic siloxanes in the presence of subtilisins. In contrast, the present claims are directed to methods of forming organic molecules by contacting a hydrolase enzyme with an organic reactant to catalyze the hydrolysis and/or condensation of the organic reactant to form the organic molecule. The hydrolase enzymes employed comprise lipase, protease, cutinase or a combination thereof; wherein the lipase enzyme is selected from the group consisting of *Candida antarctica* lipase, *Candida antarctica* lipase B, *Rhizomucor miehei* lipase, wheat germ lipase or a combination thereof; and wherein the protease enzyme and is selected from the group consisting of trypsin, papain, pepsin or a combination thereof. The present application does not employ subtilisins as described by Sakkab. The claims specifically recite these specific enzymes, as other enzymes are not able to catalyze the hydrolysis and condensation of organic reactants pursuant to the methods of the claims. In fact, as shown in Example 3 of the present application, the subtilisin protease and the cysteine protease disclosed in the Sakka publication, do not catalyze the hydrolysis and condensation of the organic reactants as defined by the claims. Accordingly, Applicants find no teaching or reference in Sakkab of the methods as defined by the claims.

"To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter, *PPG Industries Inc. v. Guardian Industries Corp.*, supra. The disclosure must be enabling to have placed it in the possession of a person of ordinary skill in the field of the invention, *In re Paulsen*, supra.

Furthermore, a generic disclosure does not by itself describe Applicants' claimed invention within the meaning of 35 U.S.C. §102. Rather, such a prior art reference must further provide a more specific, limited teaching in order to anticipate, *In re Petering*, supra; *In re Ruschig*, supra; and *In re Arkley*, supra. In view of the failure of Sakkab to teach or recognize the methods as defined by claims 1, 5, 9-16, 20 and 24-32, the reference does not enable one skilled in the art to produce the methods as recited by the claims. It is therefore submitted that Sakkab does not anticipate claims 1, 5, 9-16, 20 and 24-32 under 35 USC §102.

Applicants submit that the rejection under 35 USC §102 has been overcome. Reconsideration is respectfully requested.

Claims 1, 5, 9-16, 20 and 24-32 were rejected under 35 U.S.C. §102(a) as being anticipated by Bassindale et al (*Enzyme-catalysed siloxane bond formation*, Journal of Inorganic Biochemistry, 96, 2003, 401-403) and Bassindale et al (*Biocatalysis of Siloxane Bonds*, Polymer Preprints, 44(2), 2003, 570-571). The Examiner asserted that references teach the formation of hexamethyldisiloxane from trimethylethoxysilane using an enzymatic hydrolysis and condensation with 40 mg/mL trypsin in aqueous buffer at pH 7 and temperatures of 25 °C.

Applicants submit that the cited publications are not prior art under 35 U.S.C. §102(a) as two of the authors of the publications are co-inventors of the present application. It is well settled that disclosure to the public of one's own work constitutes a bar to the grant of a patent claiming a subject matter so disclosed, or subject matter obvious therefrom, only when the disclosure occurred more than one year prior to the date of the application, *In re Katz*, 215 U.S.P.Q. 14 (CCPA 1982). Pursuant to MPEP §716.10, co-inventors Brandstadt and Lane, co-authors of the Bassindale articles, have submitted a Declaration under 37 C.F.R. §1.132 stating that they invented the subject matter contained in those articles. As the publication date of the publications are not more than one year prior to the filing of the present application, the publications are not proper prior art to the present application.

It is therefore submitted that the rejection based on the publications should be withdrawn. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the rejections of the claims under 35 USC §§102 and 112, first and second paragraphs, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,

DINSMORE & SHOHL L.L.P.

By /Timothy W. Hagan/  
Timothy W. Hagan  
Registration No. 29,001

One Dayton Centre  
One South Main Street, Suite 1300  
Dayton, Ohio 45402-2023  
Telephone: (937) 449-6400  
Facsimile: (937) 449-6405  
e-mail: timothy.hagan@dinslaw.com

TWH/tlo  
Enclosure